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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/743,726   | 04/12/2001  | Richard A. Gambale   | B0410/7278          | 7561             |
| 22832  | 7590        | 07/15/2004           | EXAMINER            |                  |
| KIRKPATRICK & LOCKHART LLP<br>75 STATE STREET<br>BOSTON, MA 02109-1808 |             |                      | MENDEZ, MANUEL A    |                  |
|  |             | ART UNIT             | PAPER NUMBER        |                  |
|  |             | 3763                 |                     |                  |

DATE MAILED: 07/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 09/743,726             | GAMBALE ET AL.      |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Manuel Mendez          | 3763                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### **Status**

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is **FINAL**.                                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### **Disposition of Claims**

- 4) Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 5-11 is/are allowed.
- 6) Claim(s) 1-4 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### **Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### **Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### **Attachment(s)**

|   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. _____.   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |

## DETAILED ACTION

The examiner of record would like to inform applicant that a secondary search based on the subject matter of the pending claims has produced relevant prior art to the prosecution of this application. Accordingly, the following rejections are presented for applicant's review.

### Group I: Claims 1-4.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

**Claim 1** is rejected under 35 U.S.C. 102(e) as being anticipated by Hayman.

The Hayman Patent discloses an agent delivery system having a pellet containing therapeutic agent, a flexible, implantable body having a hollow interior configured to receive and retain the pellet within the interior after the body have been implanted within tissue.

**Claim 1** is rejected under 35 U.S.C. 102(e) as being anticipated by Peiler, et al.

The Peiler, et al., Patent discloses an agent delivery system having a pellet containing therapeutic agent, a flexible, implantable body having a hollow interior configured to receive and retain the pellet within the interior after the body have been implanted within tissue.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claim 2-4** are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayman in view of Leone, et al. and Fagan, et al., and in further view of Peiler, et al., and Billeter, et al. The Hayman Patent does not disclose a helical spring having individual coils which define an inside diameter suitable for retaining a pellet in position within the device and the coils being spaced a distance which permits bodily fluids to

flow into the interior of the device and yet small enough to prevent passage of the pellet from the interior of the device. However, the structural and functional limitations above are conventional in view of the teachings of Leone, et al., and Fagan, et al.

The infusion of pellets into the body using a stent (coils) can be performed within the tubular space of each one of the coils as shown by Leone, et al. or by retaining the drug within the axial tubular space created by the stent as disclosed in Fagan, et al. Moreover, the infusion of medicaments into tubular structures located within the body is a well-known concept as shown by Peiler, et al. As long as the medical device has a wall capable of retaining a drug or medicament, such drug or medicament can be deployed into the tubular body in order to be retained in the tubular structure.

Based on the observations above, a person of ordinary skill in the art would recognize that a design containing numerous helical coils would create a wall capable of retaining a drug within its interior. Therefore, the infusion of drugs or medicaments into tubular structures located within the body would have been considered an obvious design choice.

Finally, concerning **claims 3 and 4**, Billeter, et al., teaches the importance of tubular diameters in order to retain infused medicaments. In figures 1 and 3, pellets (2) are retained in the tubular structure because their diameter is greater than the diameter of the tubular medical device. Based on the teachings of Billeter, et al., a person of ordinary skill in the art would have recognized that in order to restrict the movement of pellets within a tubular medical device, the tubular structure of the holder must have a smaller diameter than the pellets. Accordingly, for a person of ordinary skill in the art,

altering the diameter of the tubular medical device (holder) in order to restrict the movement of pellets would have been considered an obvious design choice.

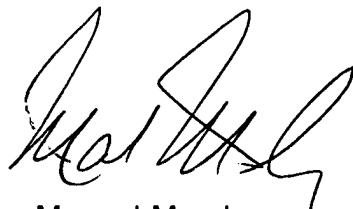
**Group II: Claims 5-8 and 9-11.**

**Claims 5-8 and 9** are allowable over the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel Mendez whose telephone number is 703-308-2221. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Manuel Mendez  
Primary Examiner  
Art Unit 3763

MM